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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,610	05/23/2001	Christoph D. Karp	NS-113	3648
32763	7590	03/24/2004	EXAMINER	
NANOSTREAM, INC.			SINES, BRIAN J	
580 SIERRA MADRE VILLA AVE.			ART UNIT	
PASADENA, CA 91107-2928			PAPER NUMBER	
			1743	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/864,610

Applicant(s)

KARP ET AL.

Examiner

Brian J. Sines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 44-52 is/are allowed.
- 6) ☒ Claim(s) 1-43 and 53-59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 102

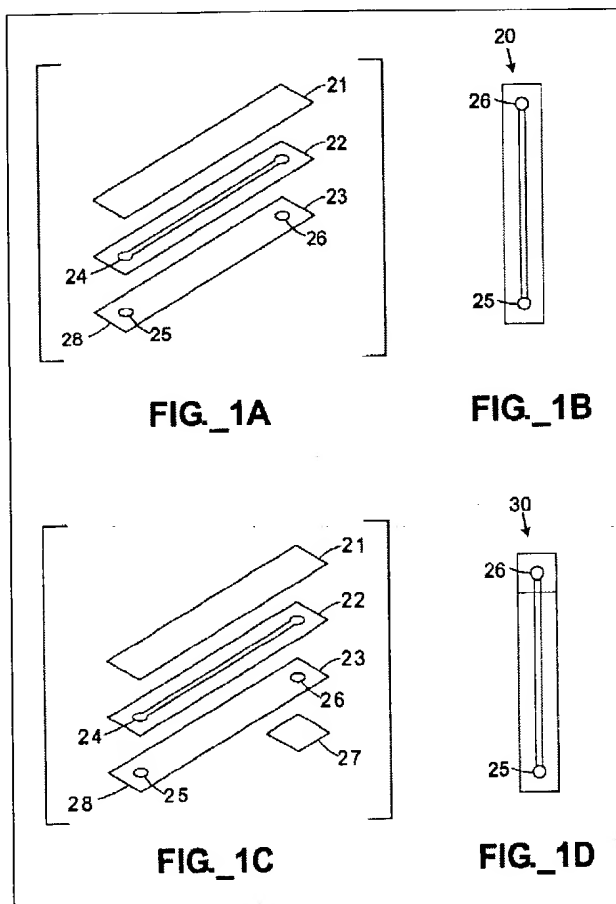
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

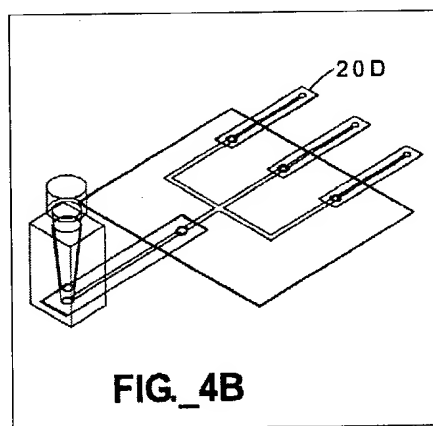
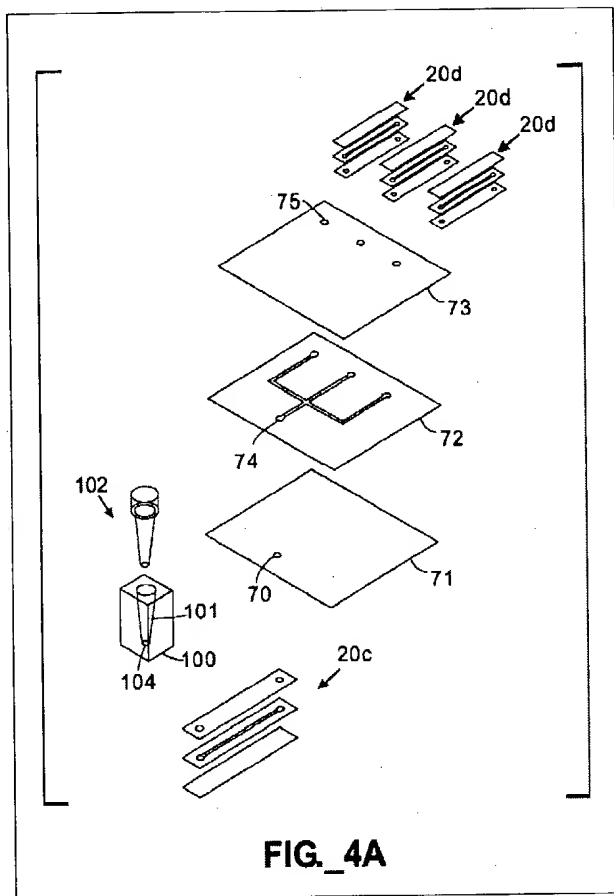
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1 – 17, 22 – 43 and 53 – 59 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Connor et al. (U.S. Pat. No. 6,536,477 B1). Regarding claim 1, O'Connor et al. teach a system comprising: a vessel (e.g., pipette tip coupling block 100) capable of holding a fluid, wherein the vessel comprises at least one substantially nonplanar wall (e.g., the tapered hole 101 comprising a conical interior surface wall, which is shaped to receive and fit a standard pipette tip 102 snugly) defining a first aperture therein; and a microfluidic device (microfluidic coupler 20 & 20c) comprising a first port (25); wherein the microfluidic device is attached to the vessel by co-locating the first port with the first aperture, such that fluid can flow between the vessel and the microfluidic device through the co-located first aperture and first port (see col. 5, lines 36 – 67; col. 8, lines 52 – 67; figures 1A – D, 4A & B).

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Regarding claims 2 and 22, the microfluidic device (microfluidic coupling device 20 & 20c) is flexible (see col. 4, lines 10 – 19). Regarding claims 3 and 23, the device may comprise sandwiched stencils (see col. 3, lines 35 – 49). Regarding claim 4, the stencil may comprise a polymeric material, such as either polyester or polyimide (see col. 3, lines 35 – 49). Regarding

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claim 5, the device may include multiple layers, wherein at least one layer is a self-adhesive tape (see col. 3, lines 10 – 67). Regarding claim 6, the self-adhesive tape layer may be double-sided tape (see col. 3, lines 60 – 67). Regarding claim 7, the microfluidic device can attach to the vessel with self-adhesive tape (see col. 3, lines 50 – 67 & col. 4, lines 1 – 9). Regarding claim 8, the adhesive may be a non-permanent adhesive, so that the microfluidic device may be removed substantially intact from the vessel device (see col. 4, lines 1 – 9). Regarding claims 9 and 10, the system comprises structure facilitating the flow of fluid between the vessel structure (100) and the microfluidic device (20c) (see col. 8, lines 52 – 67; col. 9, lines 1 – 12; figures 4A & B). Regarding claim 11, the microfluidic multi-chip module (MCM) is capable of transporting samples between one or more than one microfluidic device for continuous processing (see col. 6, lines 51 – 57 & col. 10, lines 8 – 13). Regarding claims 12 and 13, the second aperture or outlet port (26) is a vent having a semipermeable membrane (27), which can permit air to escape (see col. 3, lines 16 – 59 & col. 4, lines 39 – 67). Regarding claim 14, the second aperture (26) can alternatively be used as an exit port, rather than a vent, wherein the second aperture is in fluid communication with channel (24) (see col. 3, lines 10 – 34; col. 4, lines 53 – 60; figure 1A). Regarding claim 15, a second aperture (104) is defined in a wall of the vessel (100), and the second port is co-located with the second aperture, such that the fluid can flow between the vessel and the microfluidic device (20c) through the co-located second port and second aperture (see figures 4A & B). Regarding claim 16, the vessel may comprise a syringe pump or a pipette tip (102), which is like a pipe or tube (see col. 7, lines 36 – 53). Regarding claim 17, the system incorporates the use of a syringe pump, which is well known in the art to be cylindrical and comprise a piston for injecting fluid (see col. 7, lines 37 – 53; col. 8, lines 32 – 67 & col. 9, lines

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1 – 12). Regarding claim 24, the microfluidic device comprises an internal cover layer (first substrate layer 21) and an external cover layer (e.g., the adhesive layer placed on the outer surface of the microfluidic device 28) (see col. 3, lines 16 – 49 & col. 5, lines 7 – 21). Regarding claim 25, the vessel (100) has a circumference and the microfluidic device (20c) has a length, wherein the length of the device exceeds the circumference of the vessel (see figure 4A).

Regarding claims 26 – 28, the microfluidic device is used to sense at least one chemical or biological material in the fluid, or at least one physical property of the fluid (see col. 5, lines 36 – 61; col. 6, lines 39 – 57).

Regarding claim 29, this claim recites a process or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. Since this claim is drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claim, which are considered in determining the patentability of the apparatus itself. These recited process or intended use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The Courts have held that it is well settled that the recitation of a new intended use, for an old product, does not make a claim to that old product patentable. See *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The Courts have held that the manner of operating an apparatus does not

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differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987) (see MPEP § 2114).

Regarding claims 30 – 43, O'Connor et al. teach all of the structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02).

Regarding claims 53 and 58, O'Connor et al. teach a microfluidic apparatus (20) comprising: a first flexible layer (22) comprising at least one microfluidic channel (24) therein; and a first port (25) for communicating fluid with the at least one microfluidic channel (see col. 3, line 11 – col. 4, line 60; figures 1A – D). Regarding the recitation that at least a portion of the first layer may be wrapped around itself to form a roll or is rewindable, as recited in claim 57, this recitation is considered a functional limitation. In a claim drawn to an apparatus statutory class of invention, a functional limitation may not be divorced from any specifically recited structure or composition. A functional limitation is an attempt to define an apparatus by what it does, rather than by what it is, *as evidenced by its specific structure* (emphasis added). There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper. See *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971). A functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the art in the context in which it is used. A functional limitation is often used in association with an element to define a particular capability or purpose that is served by the recited element (see

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MPEP § 2173.05(g)). Regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). The Courts have held that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). The Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114). Therefore, since O'Connor et al. teach that their disclosed apparatus may be made from flexible materials, the prior art apparatus meets this functional ability recited by the claim (see col. 4, lines 10 – 19). Regarding claims 54 and 55, O'Connor et al. teach the use of an adhesive tape (see col.3, lines 50 – 59). Regarding claim 56, the device may comprise sandwiched stencils (see col. 3, lines 35 – 49). Regarding claim 59, the device is used for electrophoretic separation (see col. 6, lines 39 – 57).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor et al. Regarding claims 18 and 19, O'Connor et al. do not explicitly teach that the microfluidic device comprises a stencil continuously wrapped around the vessel. However, O'Connor et al. do teach that the stencil layer, which may comprise a double-sided adhesive tape, is used to construct the devices and to connect the system devices together (see col. 3, lines 60 – 67 & col. 4, lines 1 – 6). O'Connor et al. teach that a coating is placed via spin or spray coating on the bottom surface (28) of stencil layer (23) after assembly (see col. 5, lines 7 – 21). O'Connor et al. teach that a malleable stencil material aids in sealing the microfluidic coupling device with another device (see col. 4, lines 10 – 19). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success in continuously wrapping or coating a stencil layer around the connected vessel and microfluidic device in order to facilitate a securely sealed connection between the connected system components. The applicant is advised that the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a

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microfluidic device comprising a stencil continuously wrapped or coated around the vessel.

Regarding claim 20, the vessel may comprise a pipette tip (102), which comprises a cylindrical shape. Regarding claim 21, the vessel may comprise a syringe pump (see col. 7, lines 36 – 53).

Allowable Subject Matter

Claims 44 – 52 are allowed.

The following is an examiner's statement of reasons for allowance:

The cited prior art neither teach or fairly suggest a fluid sampling apparatus comprising: a cylindrical vessel, which is capable of holding a fluid, having a characteristic length and an interior wall that defines a first and a second radial aperture positioned from one another along the length of the vessel; a first moveable plunger sealingly engaged to the interior wall of the vessel; a second moveable plunger sealingly engaged to the interior wall of the vessel; and a reservoir having an inlet port in fluid communication with the first aperture and having an outlet port in fluid communication with the second aperture, wherein fluid is transferred from the vessel into the reservoir as the first and second plungers are translated outward from the vessel.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. O'Connor et al. teach various microfluidic devices and methods of use. Ashley teaches a piston syringe comprising two moveable plungers.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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